K113761

510(k) Summary

SEP 7 2012

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92.

1.0 Submitter's Information

Establishment Registration:

Famidoc Technology Co., Ltd.
Address 1: East 2/F Zhixiang Building, 71 Block Baoan District, Shenzhen 518101, Guangdong, P.R. China
Phone: +86-755-27864342
Fax: +86-755-27864151

Address 2: No. 212 Yilong Road, Hexi Industrial Zone, Jinxia, Changan Town, Dongguan , Guangdong Province, P.R.China.
Contact Person: Mr. Cao Liang
E-mail: leon@famidoc.com

2.0 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Famidoc Infrared Thermometer
Model:	FDIR-V2, FDIR-V4, FDIR-V5, FDIR-V6, FDIR-V7, FDIR-V9, FDIR-V9-3, FDIR-V10, FDIR-V15
Classification name:	thermometer, electronic, clinical
Review Panel:	General Hospital
Product Code:	FLL
Device Class:	2
Regulation Number:	880.2910

3.0 Predicate Device Information

Sponsor:	Famidoc Technology Co., Ltd.
Device:	Infrared Thermometer, model FDIR-V1
510(K) Number:	K052849

4.0 Device Description

Famidoc Infrared FDIR series Thermometers are hand-held, reusable, battery operated devices, which can measure human body temperature in two ways.
- On forehead, the skin temperature on one's forehead.
- In ear, the tympanic temperature in one's ear.

The operation principle is based on Infrared Sensor technology. The IR sensor can output different signal when measuring different object temperature or in different ambient temperature, and the ASIC can turn the signal from IR Sensor to a digital value and display it on the LCD.

The subject devices (Models: FDIR-V2, FDIR-V4, FDIR-V5, FDIR-V6, FDIR-V7, FDIR-V9, FDIR-V9-3, FDIR-V10, FDIR-V15) are the same series in Famidoc. Their design principle, intended use, indications for use, material, control keys, software and the applicable standards are the same. The differences between them are appearance, some parameters (e.g. LCD size), and some minor functions (e.g. Voice function).

5.0 Intended Use

Famidoc Infrared Thermometers, Models: FDIR-V2, FDIR-V4, FDIR-V5, FDIR-V6, FDIR-V7, FDIR-V9, FDIR-V9-3, FDIR-V10, FDIR-V15, are intended for intermittent measurement and monitoring of human body temperature by consumers in the home.

6.0 Performance Summary

The devices conform to applicable standards including ASTM E1965-98, IEC 60601-1 and IEC 60601-1-2 requirements.

7.0 Comparison to predicate device and conclusion

The subject device "Infrared Thermometers, models: FDIR-V2, FDIR-V4, FDIR-V5, FDIR-V6, FDIR-V7, FDIR-V9, FDIR-V9-3, FDIR-V10, FDIR-V15", and the predicate device "Infrared Thermometer, model: FDIR-V1" are the same series infrared thermometer in Famidoc.

The subject devices and the predicate device are the same in design principle, intended use, functions, material and the applicable standards.
Only their appearance and some characteristics (e.g. control keys, software, and voice function) are different. But the tests in this submission provide demonstrate these differences do not raise new issue of safety and effectiveness.

8.0 Conclusions

The Infrared Thermometer, Models: FDIR-V2, FDIR-V4, FDIR-V5, FDIR-V6, FDIR-V7, FDIR-V9, FDIR-V9-3, FDIR-V10, and FDIR-V15 are substantially equivalent to the predicate device.

9.0 Summary prepared date

September 6, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Cao Liang
General Manager
Famidoc Technology Company, LIMITED
No. 212 Yilong Road , Hexi Industrial Zone
Jinxia, Changan Town, Dongguan
Guangdong Province, P R China

SEP 7 2012

Re: K113761
Trade/Device Name: Famidoc Infrared Thermometer, Models: FDIR–V2, FDIR–V4, FDIR-V5, FDIR-V6, FDIR-V7, FDIR-V9, FDIR-V9-3, FDIR-V10, FDIR-V15
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 23, 2012
Received: July 23, 2012

Dear Mr. Liang

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter Smith, M.D.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Famidoc Infrared Thermometer
Models: FDIR-V2, FDIR-V4, FDIR-V5, FDIR-V6, FDIR-V7, FDIR-V9, FDIR-V9-3, FDIR-V10, FDIR-V15

Indications for Use:

Famidoc Infrared Thermometers, models: FDIR-V2, FDIR-V4, FDIR-V5, FDIR-V6, FDIR-V7, FDIR-V9, FDIR-V9-3, FDIR-V10, FDIR-V15, are intended for intermittent measurement and monitoring of human body temperature by consumers in the home.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use **X** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

8/30/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113761